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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,624	05/21/99	HIRSCHMAN S	4493-19CIP

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	3

DATE MAILED: 04/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/316,624	Applicant(s) HIRSCHMAN, SHALOM Z.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 May 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *1 and 4* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1631**.

Claims 1-4 are pending in this application.

Priority

This application is a continuation-in-part of Application Serial No. 08/838,073, filed 4/15/1997.

Specification

The use of the trademark RETICULOSE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 1 and 4 are objected to because of the following informalities: in claim 1, line 3, "microliter" should be "microliters". In claim 4, line 6, "Parenterally" should be "parenterally". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1-4 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found the specification, as filed. In the specification, applicant has stated that Product R is administered along with prednisone, the prednisone being administered in an amount of 0.0065 mg/kg/day to 1.165 mg/kg/day as set forth at page 8, lines 7-11 of the specification, and at page 13, line 16 of the specification. The specification states that prednisone is co-administered to **all** patients along with the Product R. The specification does not suggest that the Product R alone provides the amelioration of the symptoms as claimed, and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not set forth the co-administration of prednisone with the Product R.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the phrase "effective symptom ameliorating amount" in claims 1 and 4 are unclear. While the claims set forth a volume of solution to be administered, there is no correlation between the volume to be administered, and the active units present in that volume of the formulation, such that one of ordinary skill in the art would be apprised of the scope of the

invention. The specification provides two methods for making the Product R, but it is unclear that the two resulting products have the same levels of activity. There is no titration of the active Product R formulations such that one of skill in the art would be able to estimate proper dosages to be given. This is true especially in light of the wide range of volumes to be administered. 2.5 microliters (2.5×10^{-6} liters) is a miniscule amount of liquid, especially in comparison to 1 milliliter (1×10^{-3} liters) of liquid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Kochel (US Patent 5,849,196).

The claims are drawn to methods of treating symptoms of rheumatoid arthritis by the administration of Product R. The specification describes Product R as a filtered form of a product "Reticulose", made from casein, beef peptone, RNA, serum, Sodium Hydroxide and distilled water. The mixture is passed through at least a 0.45 micron filter, then a 0.2 micron filter. No chemical, or biochemical analysis of the final composition is set forth in the specification.

Kochel (US Patent 5,849,196, filed Oct. 7, 1996) discloses a composition which is derived from the filtration of "Reticulose", which can be used to treat autoimmune disorders, such as rheumatoid arthritis. Kochel discloses the preparation of the composition at columns 5 and 6, and discloses the final proportions of the components. Kochel discloses that the compositions having the lower molecular weight peptides (<8-15 Kd) are useful in the treatment of autoimmune diseases at column 3 lines 1-11. The claims recite Product R, which appears to be made by specific processes in the specification. The MPEP discusses product-by -process claims in chapter 2100: "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Kochel sets forth products derived from the known product "Reticulose" and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention. Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, the court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not

equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kochel (US Patent 5,849,196) in view of Lapin (US Patent 4,743,596).

The specification indicates that when Product R is co-administered with prednisone, that symptoms of rheumatoid arthritis are ameliorated. This rejection is based on the assumption that Applicant will amend the claims to be commensurate in scope with the disclosure.

Kochel (US Patent 5,849,196, filed Oct. 7, 1996) discloses a composition which is derived from the filtration of "Reticulose", which can be used to treat autoimmune disorders,

such as rheumatoid arthritis. Kochel discloses the preparation of the composition at columns 5 and 6, and discloses the final proportions of the components. Kochel discloses that the compositions having the lower molecular weight peptides (<8-15 Kd) are useful in the treatment of autoimmune diseases at column 3 lines 1-11. The claims recite Product R, which appears to be made by specific processes in the specification. Kochel sets forth products derived from the known product "Reticulose" and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention. Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comparative analyses and the court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Kochel does not disclose combining prednisone with Product R, or filtered Reticulose products.

Prednisone is a well known immunosuppressant which has been used for decades to treat the symptoms of rheumatoid arthritis. For example, Lapin (US Patent 4,743,596) discloses the use of prednisone in the treatment of rheumatoid arthritis, and other auto-immune diseases. Lapin discloses corticosteroids, such as prednisone, as being "dramatically effective short-term

anti-inflammatory drugs" (column 2 lines 8-26) useful in the treatment of arthritis, and specifically rheumatoid arthritis. Lapin combines the prednisone with other drugs known to effectively treat rheumatoid arthritis.

It would have been obvious to one of skill in the art at the time the invention was made to have combined the product of Kochel with prednisone formulations such as those disclosed by Lapin, for the amelioration of symptoms associated with rheumatoid arthritis. Each component has been shown to be effective in treating arthritis, and the combination of components known in the art for the same purpose has been addressed by the court. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose . . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven , 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray - dried detergent by mixing together two conventional spray - dried detergents were held to be prima facie obvious.).

Taken together, the instant invention appears to be the same or slightly different from the prior art of treating rheumatoid arthritis.

One of ordinary skill in the art at the time the invention was made would have been motivated to select and evaluate the combination of the filtered reticulose product of Kochel, and the prednisone formulations of Lapin. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success ameliorating at least one symptom of rheumatoid arthritis with the combination. Therefore, the invention as a

whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

mkz
April 3, 2000

ARDIN H. MARSCHEL
PRIMARY EXAMINER